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Alkermes

December 3, 2004

Division of Dockets Management (HFA-305),
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Draft Guidance for Industry and the Food and Drug Administration; Current Good Manufacturing Practices for Combination Products [Docket No. 2004D-0431, OC 2004219, Vol. 69 Federal Register, 59239 (October 4, 2004)]

Dear Madam/Sir:

Alkermes, Inc. appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) draft guidance "Current Good Manufacturing Practices for Combination Products". Alkermes agrees with the overall scope of this guidance that makes recommendations for achieving compliance with applicable CGMPs for the drug, device, and biological product constituent parts of a combination product and for combination products where the constituent parts of a combination are joined together. In addition, Alkermes believes that in providing this and other guidances related to combination products as defined under 21 CFR 3.2(e), is a first step in establishing best practices and achieving compliance utilizing the provisions currently available under the regulations to manufacturers of combination products (or constituent parts thereof).

Alkermes believes that this draft guidance should also apply to reprocessed device components of a drug/device, device/drug, or biological product/drug combinations, such as, drug-coated catheters.

Alkermes seeks clarification that combination products will not be subjected to higher standards or controls than an individual drug, biologic or device component of a combination product. Furthermore, Alkermes recommends that the application of the GMP requirements be applied consistent with the product classification under 503(g)(1) of the Act as determined by the primary mode of action and be binding to the Compliance Office.

The Agency proposal (Section IV, subpart A, lines 249 – 272) poses the potential danger of the Agency interpreting applications of cGMPs differently, based upon the Division or Divisions involved in making such decisions on a product by product basis and therefore

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the implementation of the cGMPs may become impractical, especially for a manufacturer of a combination product, producing multiple combination products at the same manufacturing site. Such scenarios may only be applicable to selected highly complicated combination products.

Again, thank you very much for the opportunity to present our comments on this guidance. Should Alkermes comments warrant further discussion or clarification, please feel free to contact Diane Tiernan at 617-250-1694 or me at 617-583-6547.

Sincerely,

Priya Jambhekar
Global Vice President,
Regulatory Affairs
Alkermes, Inc.